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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/695,275	10/28/2003	Bob G. Sanders	D6150CIP2/D	4689

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EXAMINER	
KHARE, DEVESH	
ART UNIT	PAPER NUMBER
1623	

DATE MAILED: 09/10/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/695,275	SANDERS ET AL.	
	Examiner	Art Unit	
	Devesh Khare	1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-17* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *14-16* is/are allowed.

6)☒ Claim(s) *1-13 and 17* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Tocopherols, tocotrienols, other chroman and side derivatives, are disclosed in the issued U.S. Patents 6,770,672, is assigned to the assignee of this invention.

Claims 1-17 are before the examiner and an action on the merits of said claims is contained herein below.

35 U.S.C. 112, first paragraph rejection

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-13 and 17 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention of record. The specification, while enabling a method of inducing apoptosis of a cell comprising administering an effective amount of a compound of formula presented in claim 14, does not reasonably provide enablement for a method for the treatment of a cell proliferative disease. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

A conclusion of lack of enablement means that, based on the evidence regarding each of the factors below, the specification, at the time the application was filed, would not

have taught one skilled in the art how to make and/or use the full scope of the claimed invention without undue experimentation.

The factors regarding undue experimentation have been summarized in *In re Wands,* 858 F.2d 731, 8 USPQ2d 1400 (Fed. Circ. 1988) as follows:

(1) The quantity of experimentation necessary (time and expense);

(2) The amount of direction or guidance presented;

(3) The presence or absence of working examples of the invention;

(4) The nature of the invention;

(5) The state of the prior art;

(6) The predictability or unpredictability of the art;

(7) The breadth of the claims; and

(8) The relative skill of those in the art.

1. QUANTITY OF EXPERIMENTATION

With regard to factor one the quantity of experimentation needed, a method for the treatment of a cell proliferative disease wherein said cell proliferative disease is a neoplastic disease, a non-neoplastic disease or a non-neoplastic disorder (see claims 7-13) would require undue experimentation. At the very least, experimentation correlative to establishing the broad spectrum of efficacy should be provided. The absence of specific disclosures or the correlation of data to support applicant's assertions, invites the skilled artisan to engage in undue experimentation.

2. GUIDANCE PROVIDED

There is little guidance given in the specification as to the specific use of an effective amount of the compound of claim 1 in a method for the treatment of a cell proliferative disease. This lack of guidance would indeed impose the burden of undue experimentation in determining the degree, if any, for the prevention of human health conditions set forth. There is not seen any guidance in the specification drawn to establishing a correlation between the use of an effective amount of the compound of claim 1 and the treatment of a cell proliferative disease. No guidance to use the compound of claim 1 a method for the treatment of a cell proliferative disease is provided.

3. WORKING EXAMPLES IN SPECIFICATION

The EXAMPLES advanced in the instant specification are not seen as sufficient to support the breadth of the claims for the treatment of a cell proliferative disease wherein said cell proliferative disease is a neoplastic disease, a non-neoplastic disease or a non-neoplastic disorder. It is noted that Examples 15-20 provide cancer models and the doses of the drug used.

4. NATURE OF THE INVENTION

It is known in this art that certain compounds have efficacy in treating specific conditions diseases associated with a cell proliferative disease such as breast cancer, prostate cancer and skin cancer. The exact mechanism of action and the effects of these compounds may be found in the Abstract (Fariss et al., Cancer Res. 54,3346-51,July1, 1994)(IDS of parent application).

5. STATE OF THE PRIOR ART

The instant claimed methods are drawn to a method for the treatment of a cell proliferative disease. The following references are cited to show the state of the prior art:

Fariss et al., Cancer Res. 54,3346-51,July1, 1994.

Grisar et al. U.S. Patent 5,545,660.

6. THE PREDICTABILITY OF THE ART

To extrapolate the data from the class of compounds represented by the general structure related to α-tocotrienol, γ-tocotrienol or ε-tocotrienol of claim 1, for the treatment of a cell proliferative disease is not seen to be disclosed in the prior art. Neither the specification nor the prior art provides adequate guidance for equivocating the general structure related to the compound α-tocotrienol, γ-tocotrienol or ε-tocotrienol of claim 1, in a method for the treatment of a cell proliferative disease. The extrapolation is not seen to be used upon data which would adequately substantiate for the prevention of human health conditions set forth.

7. BREATH OF THE CLAIMS

Claims 14-16 are drawn to a method of inducing apoptosis of a cell comprising administering an effective amount of a compound of formula presented in claim 14. Claims 1-13 and 17 are drawn to a method for the treatment of a cell proliferative disease with the compound of formula presented in claim 1.

8. THE RELATIVE SKILL IN THE ART

The relative skill in the art as it relates to a method for the treatment of a cell proliferative disease with the compound of formula presented in claim 1, is that of a Ph.D. or M.D. level.

Presently, the instant specification is not seen to provide an enabling disclosure for the scope of the invention as set forth in claims, which encompass a method for the treatment of a cell proliferative disease with the compound of formula presented in claim 1. It is noted that Law requires that the disclosure of an application shall inform those skilled in the art how to use applicant's alleged discovery, not how to find out how to use it for themselves, see In re Gardner et al. 166 USPQ 138 (CCPA 1970). In the instant case, the amount of experimentation needed to verify the efficacy of the said compound of formula presented in claim 1 for the treatment of a cell proliferative disease would indeed be voluminous and unduly burdensome in view of the teachings of the instant disclosure.

2. The compounds of formula presented in claim 14 such as tocopherols, tocotrienols, other chroman and side derivatives, are disclosed in the issued U.S. Patents 6,770,672, is assigned to the assignee of this invention and claims 14-16 of the present invention recite a method of inducing apoptosis of a cell comprising the step of contacting said cell with a pharmacologically effective dose of the compounds of formula presented in claim 14. A review of the prior art revealed no references that could be appropriately applied on the method of claims 14-16.

Any inquiry concerning this communication or earlier communications from the

Examiner should be directed to Devesh Khare whose telephone number is 571-272-0653. The examiner can normally be reached on Monday to Friday from 8:00 to 4:30. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson, Supervisory Patent Examiner, Art Unit 1623 can be reached at 571-272-0661. The official fax phone numbers for the organization where this application or proceeding is assigned is (703) 308-4556 or 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

Devesh Khare, Ph.D.,J.D.
Art Unit 1623
August 27,2004

JAMES O. WILSON
SUPERVISORY PATENT EXAMINER
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